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EXAMINER	
COBANOGLU, DILEK B	
ART UNIT	PAPER NUMBER
3626	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/997,962	HANSON ET AL.	
	Examiner	Art Unit	
	DILEK B. COBANOGLU	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,19-30 and 37-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,19-30 and 37-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment received on 7/31/2008. Claims 38-40 have been newly added. Claims 16, 19-30 and 37-40 remain pending in this application.

Claim Objections

2. Claim 16 is objected to because of the following informalities: Claim 16 recites: "associating a unique tracking code with said single source, wherein said unique tracking code is unique as to a said single source". Examiner believes that there is a typographical error, and "a said single source" is not proper. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 37 is rejected under 35 U.S.C. 102(e) as being unpatentable by Brook et al. (hereinafter Brook) (U.S. Patent No. 6,170,746 B1).

A. Claim 37 has been amended now to recite a method for tracking data associated with a medical device adapted for the administration of a drug to a patient, said method comprising:

i. preparing a single source of a drug to be administered to a patient (Brook; col. 6, line 56 to col. 7, line 31),

ii. associating a unique tracking code with said single source (Brook; col. 5, lines 48-54),

iii. providing first data associated with said tracking code relating to said drug in said single source to be administered (Brook; col. 5, lines 48-54),

iv. providing second data representing an amount of said drug in said single source administered to said patient from said single source associated with said tracking code (Brook; col. 7, lines 32-50, col. 8, lines 27-65),

v. providing third data associated with disposing of said single source (Brook; col. 6, lines 36-55, col. 10, line 51 to col. 11, line 12),

vi. storing said first, second and third data in association with said tracking code on a storage device (Brook; col. 6, lines 2-19),

vii. retrieving said first, second and third data from said storage device using said tracking code, whereby said first, second and third data associated with said tracking code tracks said single source from said preparing of said source through administration of said drug to a patient to

said disposal thereof (Brook; col. 5, lines 18-35, col. 6, lines 2-19, col. 8, lines 27-65, col. 9, lines 40-53).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 16, 19-30, 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (hereinafter Walker) (U.S. Patent No. 5,651,775) in view of Brook et al. (hereinafter Brook) (U.S. Patent No. 6,170,746 B1).

A. Claim 16 has been amended now to recite a method for tracking data associated with a medical device adapted for the administration of a drug to a patient, said method comprising:

i. providing a single source of a drug to be administered to a patient (Walker; abstract, col. 2, lines 7-19),

ii. associating a unique tracking code with said single source, wherein said unique tracking code is unique as to a said single source,

iii. providing data associated with said drug in said single source to be administered from providing of said single source to said disposal of said single source (Walker; abstract, col. 2, lines 7-19, col. 10, lines 56-65),

iv. disposing of said single source (Walker; col. 10, lines 56-65),

v. storing said data in association with said tracking code on a storage device, whereby the stored data may be altered while still being associated with the same unique tracking code, and

vi. retrieving the stored data from said storage device using said tracking code, wherein the stored data tracks the administration of said drug from said source from providing of said source to said disposing of said source.

Walker fails to expressly teach "associating a unique tracking code with said single source, wherein said unique tracking code is unique as to a said single source". However, this feature is well known in the art, as evidenced by Brook.

In particular, Brook discloses "associating a unique tracking code with said single source, wherein said unique tracking code is unique as to a said single source" (Brook; abstract, col. 3, lines 15-24, col. 3, lines 32-40, col. 5, lines 48-54).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Brook with the motivation of minimizing the manual entry of tracking data and automatically update the requisite records to improve the accuracy, speed and efficiency of the drug tracking (Brook; col. 3, lines 9-14).

Walker fails to expressly teach "storing said data in association with said tracking code on a storage device, whereby the stored data may be altered while still being associated with the same unique tracking code" and "retrieving the stored data from said storage device using said tracking code, wherein the stored data tracks the administration of said drug from said source from providing of said source to said disposing of said source". However, this feature is well known in the art, as evidenced by Brook.

In particular, Brook teaches these limitations in col. 3, lines 8-24, col. 3, lines 32-40.

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Brook with the motivation of minimizing the manual entry of tracking data and automatically update the requisite records to improve the accuracy, speed and efficiency of the drug tracking (Brook; col. 3, lines 9-14).

Walker fails to expressly teach "retrieving the stored data from said storage device using said tracking code, wherein the stored data tracks the administration of said drug from said source from providing of said source to said disposing of said source". However, this feature is well known in the art, as evidenced by Brook.

In particular, Brook discloses "retrieving the stored data from said storage device using said tracking code, wherein the stored data tracks the administration of said drug from said source from providing of said source to said disposing of said source" (Brook; abstract, col. 3, lines 8-24, col. 3, lines 32-40, col. 5, lines 48-54, col. 6, lines 36-55 and col. 5, lines 18-35, col. 6, lines 2-19, col. 8, lines 27-65, col. 9, lines 40-53).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Brook with the motivation of minimizing the manual entry of tracking data and automatically update the requisite records to improve the accuracy, speed and efficiency of the drug tracking (Brook; col. 3, lines 9-14).

B. Claims 19-26 have not been amended, and Applicant does not appear to argue the separate patentability of these claims. As such, claims 19-26 are rejected for the same reasons given in the previous Office Action (paper number 6), and incorporated herein.

C. Claim 27 has been amended now to recite a method for tracking data associated with a medical device adapted for the administration of a drug to a patient, said method comprising:

i. preparation of a single source of a drug to be administered to a patient (Walker; abstract, col. 2, lines 7-19),

ii. affixing said single source in a cradle (Walker; col. 6, lines 20-37),

iii. providing a label having a bar code corresponding to a unique tracking code affixed to at least one of said source and said cradle (Walker; col. 6, lines 20-37), wherein said unique tracking code is unique as to said single source,

iv. identifying data associated with said drug in said single source and said patient (Walker; col. 1, lines 54-67, col. 2, lines 28-47),

v. storing said data in association with said unique tracking code on a storage device (Walker; col. 5, lines 26-40, col. 13-47),

vi. administering a quantity of said drug to a patient from said single source (Walker; col. 5, lines 26-40, col. 13-47),

vii. disposing of said single source after administration of said drug to a patient (Walker; col. 10, lines 41-65),

viii. updating said data and said quantity of said drug administered in association with the same unique tracking code on said storage device, and

ix. retrieving said data from said storage device using said unique tracking code, wherein said data tracks said drug and said single source from preparation of said source to disposing of said source.

Walker fails to expressly teach "a unique tracking code is unique as to a single source". However, this feature is well known in the art, as evidenced by Brook.

In particular, Brook discloses "a unique tracking code is unique as to a single source" (Brook; abstract, col. 3, lines 15-24, col. 3, lines 32-40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Brook with the motivation of minimize the manual entry of tracking data and automatically update the requisite records to improve the accuracy, speed and efficiency of the drug tracking (Brook; col. 3, lines 9-14).

Walker fails to expressly teach "updating said data and said quantity of said drug administered in association with the same unique tracking code on said storage device". However, this feature is well known in the art, as evidenced by Brook.

In particular, Brook discloses "updating said data and said quantity of said drug administered in association with the same unique tracking code on said storage device" (Brook; abstract, col. 5, lines 30-36, col. 10, line 51 to col. 11, line 12).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Brook with the motivation of minimize the manual entry of tracking data and automatically update the requisite

records to improve the accuracy, speed and efficiency of the drug tracking (Brook; col. 3, lines 9-14).

D. Claims 28-30 have not been amended, and Applicant does not appear to argue the separate patentability of these claims. As such, claims 28-30 are rejected for the same reasons given in the previous Office Action (paper number 9), and incorporated herein.

E. Newly added claims 38-40 recites the method of claims 16, 27 and 37 wherein said unique tracking code is stored in said storage device in association with the identification of a patient to be administered said drug (Walker; abstract, col. 2, lines 7-19, col. 3, lines 26-30, col. 9, lines 12-15).

Response to Arguments

7. Applicant's arguments filed 7/31/2008 have been fully considered but they are not persuasive. Applicant's arguments will be addressed below in the order in which they appear.

A. In response to Applicant's arguments about Brook does not teach "the ability to associate a unique tracking code with a single source"; Examiner respectfully submits that claim 37 recites "associating a unique tracking code with said single source" and Brook teaches "A drug tracking system and method for use in hospitals, pharmacies, etc. uses a portable barcode scanning and printing system to reduce errors in the tracking information and to facilitate the ease and efficiency of the drug tracking operation." in abstract; "The portable scanning and

printing system 20 includes a number of input means for entering data into the system 20 including a barcode scanner 22, a keyboard 24 and a radio frequency communication interface 26. The barcode scanner 22 is operated to scan a barcode **containing** National Drug Code (NDC) information that identifies **a drug**, i.e. the drug's name and its strength." In col. 5, lines 48-54; and "In accordance with another feature of the present invention, the portable scanning and printing system automatically prompts the user to pick drugs identified by pick-list information received from the host system. After prompting the user to pick a particular drug, by displaying information identifying the drug to be picked for a particular destination, **the user scans a barcode associated with the identified drug**, **the barcode typically being located on the shelf supporting the drug, or on a drug container**. Examiner interprets that the barcode is not only a NDC code, but includes NDC code information in it and the code identifies only one drug, or one container of specified drug.

B. In response to Applicant's arguments about Brook does not teach ""a storage device on which information is stored"; Examiner respectfully submits that Brook teaches "More particularly, the portable scanning and printing system includes a memory for collecting data, a display, a printer and a number of input means including a barcode scanner, a keyboard or keypad, and a wireless communication interface. The wireless communication interface allows the portable scanning and printing system to communicate with **a host system having a memory for storing drug tracking records** wherein the host system

automatically updates the drug tracking records from information transmitted thereto by the portable scanning and printing system." In col.3, lines 15-24.

C. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant argues about Brook does not teach "tracking the amount of drug administered to a patient from a single source associated with a unique tracking code"; and Examiner respectfully submits that Walker teaches "A medication delivery and monitoring system and methods whereby drugs are safely delivered to a patient, monitored in real-time during delivery and crucial events are recorded during delivery to provide real-time, on-line information and detail for an audit trail." (abstract), and "The scanning module employs bar code or other digital indicia scanners to read labels affixed to the syringe label cradle. Information contained on the label comprises a code identifying a drug contained in an associated syringe, size of the syringe, syringe type, preparer of the drug, and any expiration data associated with the drug. The scanning module readers are also used to monitor syringe plunger movement as a drug is administered thus acquiring drug administration dynamics in real time. Scanning by the scanning module may comprise two scanners, one for reading drug related codes and one for tracking advancement of an associated syringe

plunger, thereby determining delivery rate and volume of administered drugs." In col. 2, lines 7-19).

D. In response to Applicant's arguments about Brook does not teach "a system which can track a single source to disposal of the source"; Examiner respectfully submits that Brook teaches "At block 172 the processing unit 32 creates a dispense record in the memory 34 using the pick-list record maintained in the memory 34 where the dispense record confirms the removal of a particular drug from the location. The dispense record identifies the drug including its strength, the quantity removed i.e. dispensed, and the destination of the drug after it was removed from the location. At block 172, the dispense record is also transmitted via the communication interface 26 to the host system so that the host system can update its pick-list records 48 in its memory." In col. 10, line 51 to col. 11, line 12.

E. In response to Applicant's arguments about Brook does not teach "a unique tracking code with the third data, and store the third data in association with a unique tracking code on a storage device"; Examiner respectfully submits that Brook teaches "At block 172 the processing unit 32 creates a dispense record in the memory 34 using the pick-list record maintained in the memory 34 where the dispense record confirms the removal of a particular drug from the location. The dispense record identifies the drug including its strength, the quantity removed i.e. dispensed, and the destination of the drug after it was removed from the location. At block 172, the dispense record is also transmitted

via the communication interface 26 to the host system so that the host system can update its pick-list records 48 in its memory." In col. 10, line 51 to col. 11, line 12.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

9. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DILEK B. COBANOGLU whose telephone number is (571)272-8295. The examiner can normally be reached on 8-4:30.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher L. Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. B. C./
Examiner, Art Unit 3626
12/1/2008

/Robert Morgan/
Primary Examiner, Art Unit 3626